MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting

Fax to 1-800-FDA-0178
Or mail to address on back

Page ____ of ____

Form approved: OMB No.
See OMB statement on reverse

FDA Use Only

Triage unit sequence #

A. Patient information

1. Patient ID	2. Age at time of event or Date of birth:	3. Sex ☐ F ☐ M	4. Weight ☐ lb ☐ kg	5. Height ☐ in ☐ cm

B. ■ Adverse event and/or ■ Product problem (see back)

2. **If adverse event, patient outcome** (check all that apply)

- ☐ death _____ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ none of the above (explain in B3)

3. **Describe event or problem**

4. **Date of event**

DRAFT: 10/1/98
(Do not use for reporting)

5. **Relevant tests/laboratory data,** including dates

6. **Other relevant history, including preexisting medical conditions** (e.g., race, allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

7. **Concurrent medical products** (including dietary supplements) and therapy dates (exclude treatment of event)

C. Suspect product(s) (fill in those sections that apply)

1. **Brand name** (include strength and dosage form)
   a.
   b.

2. **Generic name** (or ingredients) **or type of device**
   a.
   b

3. **Dose, route & frequency used**
   a.
   b.

4. **Therapy dates** (or implant/explant dates) from/to (or best estimate)
   a.
   b.

5. **Diagnosis for use** (indication)
   a.
   b.

6. **Exp. date**
   a.
   b.

7. **Product is**
   a. ☐ RX ☐ OTC
   b. ☐ RX ☐ OTC

8. **Event abated after use stopped or dose reduced?**
   a. ☐ yes ☐ no ☐ n/a ☐ unk
   b. ☐ yes ☐ no ☐ n/a ☐ unk

9. **Event reappeared after reintroduction?**
   a. ☐ yes ☐ no ☐ n/a
   b. ☐ yes ☐ no ☐ n/a

10. **Use of device**
    a. ☐ initial ☐ reuse ☐ unknown
    b. ☐ initial ☐ reuse ☐ unknown

11. **Product #(s)** (fill in those that apply)

	a.	b.
lot #		
NDC #		
model #		
catalog #		
serial #		
other #		

12. **If device, operator is** ☐ health professional ☐ lay user/ patient ☐ other: _____

13. **Product available for evaluation?** (do not send to FDA)
    a. ☐ yes ☐ no ☐ returned to manufacturer on _____
    b. ☐ yes ☐ no ☐ returned to manufacturer on _____

14. **Label available?** (see back)
    a. ☐ yes ☐ no ☐ unk
    b. ☐ yes ☐ no ☐ unk

15. **Manufacturer name and address**
    a.
    b.

16. **Directions for use** (see back)
    a.
    b.

D. Reporter (see confidentiality section on back)

1. **Name, address** (optional: email/fax)

2. **Phone number**

3. **Date of this report**

4. **Health professional?** ☐ yes ☐ no

5 **Occupation/specialty**

6. **Attachments included?** ☐ yes ☐ no

7. **Follow-up report?** ☐ yes ☐ no
   FDA ref# (if known) _____

8. **Also reported to**
   ☐ manufacturer
   ☐ medical facility
   ☐ distributor

9. **If you do not want your identity disclosed to the manufacturer, place an "X" in this box.** ☐

FDA Form 3500 ( ) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

ADVICE ABOUT VOLUNTARY REPORTING

(For a complete set of instructions or to report via internet, visit the MedWatch Homepage: www.fda.gov/medwatch)

Report experiences with:

- medications (drugs or biologics, excluding vaccines)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- cosmetics

If event involves a vaccine, it should be reported to the Vaccine Adverse Event Reporting System (VAERS) on form VAERS-1, available by calling 1-800-822-7967.

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent *permanent* impairment or damage

Report serious adverse events even if:

- you're not certain the product caused the event
- you don't have all the details

Report product/use problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- device malfunctions
- therapeutic failures
- product confusion (caused by name, labeling, design, or packaging)

How to report:

- just fill in the sections that apply to your report
- attach additional pages if needed and check yes box in block D6
- use a separate form for each patient

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-1088 to report by phone or for a copy of a complete set of instructions

Note:

- **Block C14** – If reporting on a drug product problem or on a special nutritional, please attach labeling/packaging, if available, and check *yes* in block D6.
- **Block C16** – Applicable to special nutritionals only; please provide directions for use as listed on the product label.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise, by checking Block D9. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.